

## Actions Taken by FDA Center for Veterinary Medicine

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The following corrections or additions to the January 1999 list were published in the Federal Register in August 1999

### New Approvals

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**ANADA Number: 200-245**

Pioneer Product: 096-676  
Trade Name: Derma-Vet Cream  
Ingredients: Neomycin sulfate, nystatin, triamcinolone acetonide, thiostrepton  
Sponsor: Med-Pharmex, Inc.  
Approval Date: June 7, 1999  
Status: Prescription only  
Route: Topical  
Species: Dogs and cats  
Drug Form: Cream  
Concentration: Each gram contains neomycin sulfate equivalent to neomycin base 2.5 mg, nystatin 100,000 units, triamcinolone acetonide 1.0 mg, thiostrepton 2500 units.  
Indications: For the management of dermatologic disorders in dogs and cats, characterized by inflammation and dry or exudative dermatitis, particularly those caused, complicated or threatened by bacterial or candidal (*Candida albicans*) infections. Also of value in treating eczematous dermatitis, contact dermatitis and seborrheic dermatitis; and as an adjunct in the treatment of dermatitis due to parasitic infestation.

21CFR 524.1600a

### Supplemental Approvals

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**NADA Number: 038-233**

**This supplemental application expands the indications to include use of this ear implant to improve feed efficiency in steers kept in confinement for slaughter.**

Trade Name: Ralgro<sup>®</sup> Magnum  
Ingredients: Zeranol  
Sponsor: Schering-Plough Animal Health Corp.  
Approval Date: June 25, 1999  
Status: Over the counter  
Route: Subcutaneous  
Species: Cattle  
Drug Form: Implant  
Concentration: 72 milligrams per implant  
Indications: For increased rate of weight gain and improved feed efficiency in steers fed in confinement for slaughter.  
Tolerance: Not needed  
Exclusivity: 3 years

21CFR 522.2680

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**NADA Number: 040-209**

**This supplemental application provides for a change in the name of a duck pathogen. This supplement reflects the taxonomic change for *Pasteurella anatipestifer* to *Riemerella anatipestifer*.**

Trade Name: Rofenaid® 40  
Ingredients: Sulfadimethoxine, ormetoprim  
Sponsor: Roche Vitamins, Inc.  
Approval Date: June 15, 1999

21CFR 558.575

### Change of Sponsor

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The following NADAs previously owned by Roussel-UCLAF SA, Animal Health Division (drug labeler code 012579) have been transferred to Hoechst Roussel Vet (drug labeler code: 012799):

130-951  
131-310  
138-612  
140-824  
140-897  
140-992

### Suitability Petition Action

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Number: 99P-2733/CP1  
Sponsor: Wildlife Laboratories, Inc.  
Petition: Request permission to file an ANADA for a generic new animal drug, ketamine hydrochloride, which differs from the pioneer product, Vetalar, Fort Dodge Animal Health, Division AHP Corp., NADA 045-290 by the following characteristic: The generic product will provide for a product containing 200 milligrams per milliliter ketamine hydrochloride whereas the pioneer product contains 100 milligrams per milliliter ketamine hydrochloride.  
Action: Filed on August 12, 1999

### Technical Amendment

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In the Final Rule published in the Federal Register of April 30, 1999 (Green Book update of April 1999, Section VIII, page 8.26) FDA published a document reflecting approval of Pliva d.d.'s ANADA 200-232 for use of Geomycin 200 (oxytetracycline injection) in cattle and swine. The amendment to the regulation failed to state that the product is **not** for use in lactating dairy cattle. At this time, the regulations in 21 CFR 522.1660 are amended to reflect the limitation in the approval.